

Decision Memo for Transmyocardial Revascularization for Severe Angina (CAG-00004N)

Decision Summary

Rescind the current instruction (35-94, CIM) which excludes coverage of this service, replacing it with an instruction providing for coverage of this surgical procedure when used to treat patients with severe angina, which has been refractory to medical therapy.

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Decision Memo

December 30, 1998

Recommendation:

Rescind the current instruction (35-94, CIM) which excludes coverage of this service, replacing it with an instruction providing for coverage of this surgical procedure when used to treat patients with severe angina, which has been refractory to medical therapy.

Basis for Recommendation:

We have reviewed the material submitted by several manufacturers of the lasers used in this procedure. We have also reviewed the meetings and findings of the FDA review of the lasers used in the procedure. The FDA review did not require the degree and length of patient follow-up which we usually require before approving this type of procedure. However, one manufacturer, Eclipse Surgical Technologies, Inc., has submitted substantial additional documentation on the medical effectiveness of this procedure for patients which appears to answer the questions we had raised regarding the longer-term medical effectiveness of this procedure.

Specifications for Coverage:

Research on the appropriate uses of this technology are continuing. In addition, variations on this procedure, specifically a percutaneous application of TMR, is currently under study. In view of the probability that additional uses of this technology may be approved over the next few years, we believe a general instruction, which limits coverage to those uses which have been approved or cleared by the Food and Drug Administration (FDA) is the most efficient approach. This has the effect of limiting the need for extensive revision of the instruction. We would, of course, restrict or refuse coverage should evidence of medical effectiveness of these new uses not be sufficient; however, in view of our discussions with the industry and their understanding of our information needs, it is unlikely that this problem will arise.

We therefore propose to cover TMR as a late or last resort for patients with severe (Canadian Cardiovascular Society classification Classes III or IV) angina (stable or unstable), which has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages. In addition, the angina symptoms must be caused by areas of the heart not amenable to surgical therapies such as PTCA, stenting, coronary atherectomy or coronary bypass. Coverage is further limited to those uses of the laser used in performing the procedure which have been approved by the FDA for the purpose for which they are being used.

Patients would have to meet the following additional selection guidelines: (1) an ejection fraction of 25% or greater; (2) have areas of viable ischemic myocardium (as demonstrated by diagnostic study) which are not capable of being revascularized by direct coronary intervention; and (3) have been stabilized, or have had maximal efforts to stabilize acute conditions such as severe ventricular arrhythmias, decompensated congestive heart failure or acute myocardial infarction.

Coverage would be limited to physicians who have been properly trained in the procedure. Providers in which this service is performed must also document that all ancillary personnel, including physicians, nurses, operating room personnel and technicians, have been trained in the procedure and the proper use of the equipment involved. Coverage is further limited to providers which have dedicated cardiac care units, including the diagnostic and support services necessary for care of patients undergoing this therapy. In addition, these providers must conform to the standards for laser safety set by the American National Standards Institute (ANSI Z39.1).

Next Action:

If approved, replace current instruction (CIM 35-94), with draft instruction (copy attached) setting forth new coverage.

Approval/disapproval:

Approved: _____ Date: _____

Disapproved: _____ Date: _____

Comments: _____

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